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10/530,326	04/05/2005	Steffen Hasenzahl	032301.608	4709
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EXAMINER WELTER, RACHAEL E				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/530,326

Applicant(s)

HASENZAHN ET AL.

Examiner

RACHAEL E. WELTER

Art Unit

1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Claim Status

Claims 1-3 are pending. Claims 4-5 are cancelled.

Acknowledgements

Receipt of the amendment and remarks/arguments filed on 10/5/09 is acknowledged.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See page 9 of the instant specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

In response to the specification objection, applicant requests clarification. Applicant wants to know if the Office wishes to have the identification of the source or the access information deleted.

As noted above, the examiner notes that the hyperlink must be deleted. If applicant wishes to replace the hyperlink with the electronic journal name, volume, issue, and page numbers, applicant may do so.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-2 rejected under 35 U.S.C. 102(b) as being anticipated by Shimizu et al (US Publication No. 2002/0102369) as evidenced by Scholz et al (US Patent No. 6,951,642) is maintained.

Shimizu et al teach a cellulose ester dope composition comprising Aerosil R 972V and benzoin (see paragraph 0272); example 21). As evidenced by Scholz et al, benzoin is a polymerization initiator used in moisturizing skin treatment compositions that aids in the copolymerization of (meth) acrylate and various comonomers (column 9, lines 53-61). Furthermore, as evidenced by the instant specification, Aerosil R 972V is a hydrophobic highly disperse silicon dioxide type that is particularly suitable for the composition (pg. 11, lines 19-27). As such, it is the position of the examiner that Aerosil R 972V exhibits the instant tamped density, water-wettable contents, and BET surface area.

Response to Arguments

Applicant's arguments filed 10/5/09 have been fully considered but they are not persuasive.

Applicant argues that claim 1 has been amended to clearly identify the composition as a pharmaceutical or a cosmetic formulation. Applicant argues that

suitable cosmetic and pharmaceutical active ingredients are exemplified in the specification and submits that one of ordinary skill would understand what an "active ingredient" is under the circumstances. Applicant notes that Shimizu is not directed to a pharmaceutical composition or a cosmetic composition.

In response to applicant's arguments and amendments, the examiner notes that instant claim 1 is drawn to a pharmaceutical or cosmetic ingredient and not an active ingredient. Additionally, applicant has not defined such an ingredient nor an "effective amount" in the specification and the rejection above provides evidence (Scholz et al) that benzoin is a pharmaceutical or cosmetic ingredient. As such, it is the position of the examiner that the rejection above still reads on the instant claims. A way to overcome the rejection and distinguish the instant composition from the prior art would be to specify the pharmaceutical or cosmetic ingredients in the instant formulation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The rejection of claim 3 rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu et al (US Publication No. 2002/0102369) as evidenced by Scholz et al (US Patent No. 6,951,642) is maintained.

The disclosure of Shimizu et al is discussed above.

Shimizu et al do not teach an amount of Aerosil R 972V that is from 0.01 to 30 wt.% but rather teach an amount that overlaps with the instant amount. Shimizu teaches that the silicon dioxide particles can be present in an amount of 0.005-0.3 wt.% (column 33, lines 45-48).

However, it would have been obvious to an artisan of ordinary skill at the time the invention was made to modify and optimize the amount of Aerosil R 972V in the composition of Shimizu et al. Optimization of parameters is a routine practice that would be obvious to a person of ordinary skill in the art to employ and reasonably expect success. One would have been motivated to determine the optimal amount of each ingredient in order to best achieve the desired results, which ultimately depends on the desired matting effect and transparency. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) & MPEP 2144.05.

Response to Arguments

Applicant's arguments filed 10/5/09 have been fully considered but they are not persuasive.

Applicant argues that the deficiencies of Shimizu as evidenced by Scholz have been discussed above. Applicant argues that there are no pharmaceutical ingredients or cosmetic ingredients to optimize. Applicant submits that the silica employed by Shimizu is employed for a different function and it is an aid to facilitate flowability.

In response to applicant's arguments, the examiner directs applicant's attention to the examiner's response regarding Shimizu above, which is incorporated herein. Additionally, the examiner notes that applicant's argument that the silica is employed for a different purpose than the prior art is not persuasive. In this case, motivation to optimize the silica need not be the same as applicant's motivation. One would optimize the amount of silica in Shimizu depending on the desired matting effect and transparency.

As such, it is the position of the examiner that instant claim 3 is rendered obvious over Shimizu as evidenced by Scholz.

The rejection of claims 1-3 rejected under 35 U.S.C. 103(a) as being unpatentable over Sebillotte-Arnaud et al (US Publication No. 2002/0039976) is maintained.

Sebillotte-Arnaud et al teach a cleansing composition comprising at least one foaming surfactant, at least one hydrophobic silica, and at least one oxyalkylenated compound in a physiologically acceptable aqueous medium (paragraph 0011). According to Sebillotte-Arnaud et al, the hydrophobic silica have a specific surface area ranging from 50-500 m²/g and a compacted density preferably from 50-150 g/L

(paragraph 0021; Table 1). Sebillotte-Arnaud et al further teach that the hydrophobic silica can be an amount from 1-15 wt.% (paragraph 0018). Additionally, Sebillotte-Arnaud et al suggest that Aerosil R 972 can be used in the composition.

Although Sebillotte-Arnaud et al teach that the composition can comprise Aerosil R 972, Sebillotte-Arnaud et al do not teach a composition comprising Aerosil R 972V.

However, it would have been obvious to an artisan of ordinary skill at the time the invention was made to use a hydrophobic silica, such as Aerosil R 972V in the composition of Sebillotte-Arnaud et al. One would have been motivated to do so depending on the silica's desired compacted density and because Sebillotte-Arnaud et al suggest that the silica can have a compacted density in a range from 50-150 g/L.

Regarding the limitation, "wherein the silicon dioxide contains a maximum of 3.0 wt.% water-wettable contents," the examiner notes that Sebillotte-Arnaud et al teach hydrophobic silica. Furthermore, the instant specification provides evidence that Aerosil 972 exhibits water-wettable contents of 3 wt.% (see pg. 24, Table 6).

Response to Arguments

Applicant's arguments filed 10/5/09 have been fully considered but they are not persuasive.

Applicant argues that none of the AEROSIL products taught have a density that falls within the claimed tamped density range. Applicant notes that there is no mention of tablet or capsules, flowability of granular materials or hardness of tablets. Additionally, applicant argues that the rejection above does not include a reference

showing the existence of AEROSIL R972V and that it is not clear that a more dense, low structured silica would be suited for use in Sebillotte-Arnaud. Applicant notes that reliance on the specification for teachings is not proper.

In response to applicant's arguments, the examiner notes that applicant does not exemplify an AEROSIL product with the claimed density range, however; Sebillotte-Arnaud suggests a range of density (50-150g/L) that overlaps with the claimed density of 90-400g/L. Clearly, higher more dense, low structured silica are envisioned by the teachings of Sebillotte-Arnaud and as such, another reference showing the existence of AEROSIL R972V is not needed. The examiner notes that the specification was only used to gain a better understanding of the invention and to determine the differences between AEROSIL R972V and AEROSIL R972. In this case, it is clear from the specification and applicant's arguments that the only difference between the AEROSIL products is density. The examiner contends that the specification was not relied on for any specific teachings and all the limitations of the instant claims are suggested in the teachings of Sebillotte-Arnaud. Furthermore, in regard to applicant's argument that there is no mention of tablets, capsules, etc in Sebillotte-Arnaud, the examiner notes that the instant claims are not drawn to any type of solid dosage form. Thus, it is noted that the features upon which applicant relies (i.e., tablets, capsules, etc) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant further argues that the use of different AEROSIL products (AEROSIL R972 V vs. AEROSIL R972) result in different outcomes. Applicant argues that these outcomes would not be expected from the art of record. Applicant directs the examiner's attention to tables 7 and 8 and argues that CP1 and CP2 establish the significance for water-wettable contents making up a maximum of 3.0 wt.% limitation and also density.

In response to applicant's arguments, it is the position of the examiner that a prima facie case of obviousness has been established. Since Sebillotte-Arnaud teaches a cosmetic formulation comprising AEROSIL R972 with a density of 50-150 g/L, the different outcomes resulting from AEROSIL R972V would be expected. Furthermore, even if applicant is arguing that the outcomes of the AEROSIL products would be unexpected, these outcomes are not commensurate in scope with the instant claims. According to MPEP 716.02, whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." The examiner contends that Tables 7 and 8 in the specification, which show the different properties of the AEROSIL products, are all drawn to properties of tablets. However, applicant is not claiming a tablet or solid formulation. As such in order to be commensurate in scope with the instant claims, applicant needs to narrow the scope of the instant claims and limit the formulations to a tablet or solid formulation.

For the above reasons, it is the position of the examiner that the rejection above should be sustained.

Conclusion

Claims 1-3 are rejected. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **RACHAEL E. WELTER** whose telephone number is (571) 270-5237. The examiner can normally be reached 7:30-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REW

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
February 12, 2010